REMARKS

Claims 1-13 are the pending elected claims in the application with claims 14-68 presently withdrawn. Claim 1 is being amended. Claims 1 and 8 are the base claims. No new matter is being introduced by way of this Amendment.

Regarding 35 U.S.C. § 102(b) Rejections

Claims 1, 2, 6 and 7 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Raemer (U.S. Pat. No. 5,320,093).

Raemer discloses a system for rapidly restoring ventilatory drive in a patient who has been under anesthesia. In such cases, a patient's body must be cleansed of the anesthesia, neuro -muscular effects of the anesthesia must be reversed and the arterial blood CO2 tension (Pa CO2) must be sufficiently increased to stimulate pertinent ventilatory brain function to restore the patient's ability to breathe on his own. Thus, Raemer discloses a system for addressing the need to balance between hyperventilation (ridding the body of anesthesia) and hypoventilation (reducing O2 and increasing CO2 in the bloodstream) to trigger the drive (brain function) to breathe. Raemer describes a system that adds CO2 in controlled quantities to a breathing circuit based on a target blood stream CO2 level. The system determines the partial pressure of CO2 in the bloodstream of the patient (as estimated from a measured end-tidal value of respiratory partial pressure of CO2), and a feedback control subsystem utilizes the determined partial pressure of CO2 in the bloodstream to control the amount of CO2 added to the breathing circuit.

In Raemer, there is no source of pressurized air. Raemer only discloses measurement of expired/exhaled CO2, and does not suggest measuring concentration of CO2 in a gas mix delivered to the patient. Raemer does not mention use of substantially low concentrations of CO2 (less than 2%), nor the combination of CO2 at sufficiently low concentrations and pressurized air to form a gas mix for stabilizing breathing as in the claimed present invention. Raemer is solely concerned with introducing CO2 into an anesthesia gas for rapidly restoring ventilatory drive. The anesthesia gas of Ramer is not the same as the pressurized air of the present invention.

In contrast, the present invention is directed to patients who are breathing on their own (have ventilatory drive) but need to stabilize their breathing. The present invention recognizes

the therapeutic use of substantially low concentrations of CO2 for stabilizing breathing. In particular, the present invention discloses a gas mix formed of pressurized air and substantially low concentrations of CO2 for stabilizing breathing. Neither the gas mix nor the stabilizing benefits are implied or suggested by Raemer.

These patentable distinctions are recited in base Claim 1 with the terms:

"...combining pressurized air with substantially low concentrations of the carbon dioxide resulting in a gas mix;..." and

"...the gas mix effecting respiratory stability of said target."

Accordingly, Raemer does not disclose or suggest every claim element of the applicant's invention as now recited. Thus, Raemer does not anticipate base Claim 1. Dependent Claims 2, 6 and 7 depend from base Claim 1 and, thus, inherit the foregoing patentable distinction over the cited prior art. As such the § 102 rejection of Claims 1, 2, 6, and 7 should be withdrawn.

Regarding 35 U.S.C. § 103(a) Rejections

Claims 4, 5, 8, 9, 11, 12 and 13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Raemer (U.S. Pat. No. 5,320,093).

As discussed above, Raemer is directed at restoring ventilatory drive to anesthetized patients after surgery. In contrast, the present invention is directed to patients who are breathing on their own (have ventilatory drive). Raemer suggests use of CO2 only at concentrations that restore ventilatory drive (i.e. that balance between hyperventilation and hypoventilation) as discussed above. Raemer does not mention therapeutic use of substantially low concentrations of CO2 (below 2% and in particular between about 0.5% and about 1.25%) or the combination of substantially low concentrations of CO2 and pressurized air to form a respiratory stabilizing gas mix as recited in Claims 4-5, 8, 9, and 11-13.

The foregoing patentable distinctions are recited in base Claims 1 and 8 as now amended with the following language:

"...an assembly for combining pressurized air with substantially low concentrations of the carbon dioxide resulting in a gas mix; and

a patient centric ventilatory space module (PCVSM) coupled to the assembly providing the resulting gas mix for inhalation by a given target, said inhalation of the gas mix effecting respiratory stability of said target." (See Claim 1 as now amended), and

"...providing a substantially low concentration of carbon dioxide; and

combining pressurized air with the carbon dioxide to form a gas mix having stabilizing effects on breathing, the pressurized air enabling the carbon dioxide at low concentrations in the gas mix to have stabilizing effects on target respiratory systems." (See Claim 8).

Claims 4-5 depend from base Claim 1 and Claims 9, 11-13 depend from base Claim 8. Each dependent claim inherits the recited claim limitations of the respective base claim and thus also patentably distinguishes over the cited art.

Accordingly, the § 103 rejection of Claims 4-5, 8, 9, and 11-13 is believed to be overcome. Withdrawal of this rejection is respectfully requested.

Claims 3 and 10 have been rejected to under 35 U.S.C. § 103(a) as allegedly being unpatentable over Raemer (U.S. Pat. No. 5,320,093) in view of Pauley (U.S. Pat. No. 5,975,078).

Pauley discloses an apparatus for monitoring respiration of a patient being ventilated through a flexible gas reservoir of an anesthesia machine that includes a facemask. As discussed above, Raemer suggests use of CO2 only at concentrations that restore ventilatory drive (i.e. that balance between hyperventilation and hypoventilation). Neither Raemer nor Pauley, alone or in combination, mention therapeutic use of substantially low concentrations of CO2 or the combination of substantially low concentrations of CO2 and pressurized air to form a respiratory stabilizing gas mix as recited in base Claims 1 and 8.

Claim 3 depends from base Claim 1 and Claim 10 depends from base Claim 8. Each dependent claim inherits the recited claim limitations of the respective base claim and thus also patentably distinguishes over the cited art.

Accordingly, the § 103 rejection of Claims 3 and 10 is believed to be overcome. Withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If

the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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